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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/989,342	11/20/2001	Robert C. Simpson	13421.0002.NPUS00	5345

26720 7590 03/09/2006
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EXAMINER

WILLIAMS, CATHERINE SERKE

ART UNIT PAPER NUMBER

3763

DATE MAILED: 03/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/989,342

Applicant(s)

SIMPSON, ROBERT C.

Examiner

Catherine S. Williams

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 October 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,7-12,15-18,51,52,56 and 57 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,7-12,15-18,51,52,56 and 57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2,7-8,10-12,15,51-53 and 56-57 are rejected under 35 U.S.C. 102(b) as being anticipated by Pevsner (USPN 4,159,022). Regarding claims 1,11,15,52 and 56, Pevsner discloses a catheter delivery system that includes a delivery housing (21) with a single cavity (inside of 53) that has at least one cylindrical and conical sidewall (53) having a proximal end (at # 59) and a distal end (65), the distal end being connected to a distal end piece (67), thereby defining the single inner cavity. See figure 4. The distal end piece defines the upper border of the inner cavity. See figure 4. The distal end piece includes a dispensing aperture (aperture in 67) such that a loaded catheter (13) in the inner cavity can be extracted from the inner cavity through the dispensing aperture. See figure 1 and 3:60-4:6. The dispenser including the dispensing aperture is considered made of semi-rigid material. Even though Pevsner does not disclose the type of material the device is made from, all material has some degree of rigidity (depending on the reference point or value) and is therefore semi-rigid. The term semi-rigid is a relative term and without a reference point or reference value the term semi-rigid is a broad limitation that is met by any material.

Regarding claim 1 and the new claim language of “for manually delivery a catheter into a patient’s body”, Pevsner meets this limitation. The catheter (13) is delivered by the force of fluid

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that is provided by the syringe (87). See 3:67-4:3. The syringe shown in figure 1 is clearly a manually actuated syringe. Since the syringe is activated manually and activation of the syringe causes the catheter (13) to be delivered into the patient's body, the device is "for manually delivering a catheter into a patient's body".

Regarding claims 2, 12, 51 and 53, the sidewall (53) of the delivery housing (21) is attached to a proximal end piece (55) which further defines the inner cavity. See figure 1. The proximal end piece defines a loading aperture (hole in cap see 3:5) such that the catheter (13) may be loaded or adjusted into the inner cavity through the loading aperture. See figure 4 and 3:30-45. Regarding the new claim language of claim 51, the proximal end piece (55) as shown in figure 1 defines the proximal boundary of the inner cavity. Column 3 lines 37-45 describes how the catheter is loaded into the cavity.

Regarding claims 6 and 55, the dispenser is capable of being positioned in either hand of a user such that the distal end is directed toward the user's thumb and index finger so that the catheter contained within the inner cavity may be completely extracted through the dispensing aperture. Due to the amount of functional language in these two claims, the examiner reminds applicant that functional language is given limited patentable weight. As long as a prior art reference, while meeting the structural limitations of the claimed device, is capable of accomplishing the recited function, then the claimed device does not overcome the cited prior art.

Regarding claims 10 and 57, the inner cavity of the delivery housing (21) entirely confines the portion of the catheter that will enter the patient during the procedure except the portion of the catheter that is already extending from the delivery housing into the catheterizing

tube 11. See figure 1 and 3:45-4:5. It is noted that “entirely confines” is being read broadly in the sense that the delivery housing sidewall is a solid structure that entirely confines the portion of the catheter that is shown in figure 1 and the text cited above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pevsner. Pevsner meets the claim limitations as described above but fails to include the sidewall taking the shape of a polyhedron.

At the time the invention was made, it would have been an obvious matter of design choice to make the sidewall of Pevsner polyhedral in shape. Applicant has not disclosed that having the sidewall polyhedral in shape serves any advantage or particular purpose or solves a stated problem. Furthermore, one of ordinary skill would expect Pevsner's delivery housing and applicant's invention to perform equally well with either a cylindrical or a polyhedral housing because either shape would perform the same function of entirely confining a portion of a catheter for insertion into a patient's body equally well considering either shape would provide a single inner cavity. Therefore, it would have been prima facie obvious to modify Pevsner to obtain the invention as specified in claim 9 because such a modification would have been

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considered a mere design consideration which fails to patentably distinguish over the prior art of Pevsner.

See also *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966) (The court held that the configuration of the claimed disposable plastic nursing container was a matter of choice which a person of ordinary skill in the art would have found obvious absent persuasive evidence that the particular configuration of the claimed container was significant.).

Claims 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pevsner. Pevsner meets the claim limitations as described above but fails to include the method steps of loading the catheter into the dispenser manually, mechanically or through an automated process.

Pevsner does disclose that the catheter is loaded into the dispenser through some type of loading process and outlines all the steps required to achieve a loaded catheter. See 3:30-60. Pevsner only fails to teach whether this process is manual, mechanical or automated. Pevsner also discloses that the catheter during the loading process is “forced, by hand, back through the mounting protrusion...” [emphasis added] See 3:55.

Therefore at the time of the invention, it would have been obvious to load the catheter manually since Pevsner already discloses a portion of the loading process being conducted manually.

Additionally, it would have been obvious to load the catheter through a mechanical or an automated process since the court has held that broadly providing an automatic or mechanical means to replace a manual activity which accomplished the same result is not sufficient to distinguish over the prior art.

See *In re Venner*, 262 F.2d 91, 95, 120 USPQ 193, 194 (CCPA 1958). The court held that broadly providing an automatic or mechanical means to replace a manual activity which accomplished the same result is not sufficient to distinguish over the prior art.

Response to Arguments

In response to applicant's argument that Pevsner does not deliver a catheter to a body of a patient in a manual manner, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The newly added claim language is broad and does not provide a function that thereby provides structural limitations. As stated in the above rejection, the delivery of the catheter (13) is in a manual manner since the syringe (87) is a manual syringe and must be actuated by hand. Since the syringe is actuated by hand and actuation of the syringe directly causes delivery of the catheter (13), the catheter is thereby delivered at least in part manually.

Applicant states that no mention or suggestion is made by Pevsner of having a dispensing aperture/hole for extracting a loaded catheter from the inner cavity of the system. Attention is drawn to figure 1 that clearly shows the loaded catheter (13). In the above rejection, the dispensing aperture is indicated as the aperture in element 67 and reference is made to figure 4. Figure 4 is an exploded view of Figure 1. One can see that the loaded catheter (13) in figure 1 will be extracted through the aperture of element 67 during the step of delivery as mentioned in the above rejection.

Applicant further argues that the dispensing aperture of the instant invention and element 67 of Pevsner are not equivalent. The above rejection is an anticipation rejection and therefore equivalency is not an issue. The above rejection is clearly stating the aperture of element 67 in Pevsner is the same structure as the dispensing aperture in the instant invention. Regarding the functional language of “can be extracted from the inner cavity” (claims 1 and 11), Pevsner discloses structure that meets the claim limitations and even shows a catheter that is delivered through the dispensing aperture. Regarding device claim 1, the device of Pevsner clearly is capable of having a catheter extracted from the inner cavity since the prior art teaches a catheter positioned and moving within the device as it would if one were to choose to extract it from the inner cavity. Furthermore, Pevsner meets method claim 11 in much the same way. Functional language is given more weight in method claims; even with the additional weight the functional language in claim 11 is written in optional language, i.e. can be extracted. The term “can” clearly conveys that applicant is not definitely stating that the catheter is extracted only that it can be extracted. Clearly, even in the case of the method claim where the functional language is given added weight, the prior art still reads on the limitations.

Applicant argues that Pevsner does not teach a proximal end piece that simultaneously defines the cavity and a loading aperture. The only newly recited structure is that the proximal end piece simultaneously defines the cavity and defines the loading aperture. This is clearly shown in figure 1 where the aperture in proximal end piece (55) defines the proximal boundary of the cavity and is still the aperture that was used as a loading aperture and still is technically a loading aperture. Furthermore, the claim language of “such that a catheter can be loaded into or adjusted in the single cavity through the loading aperture” is functional and does not provide any

additional limiting structure. Regardless, Pevsner meets this functional language directly because the catheter is loaded through the aperture in the proximal end piece and then into the cavity as claimed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine S. Williams whose telephone number is 571-272-4970. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas D. Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in cursive script that reads "Catherine S. Williams".

Catherine S. Williams

March 6, 2006